AUG 3 1 2004

Oey, Jan

From: Schultz, Jill [Jill.Schultz@covance.com]
Sent: Tuesday, August 31, 2004 10:08 AM
To: Jan Oey (E-mail); Larson, Mary; Rettig, Stephanie
Cc: Downey, Pamela C.; Bentley, Mark; Boyeson, Michael; Schultz, Jill
Subject: RE: CCLS Specifications for TESMCFS/01/04

Jan, can you respond to questions 1, 2, and 3 from Pam?

Mary/Stephanie, please comment on quantity of bulk supplies being supplied at startup (question 4).

Thank you,

Jill

-----Original Message-----
From: Downey, Pamela C.
Sent: Tuesday, August 31, 2004 9:02 AM
To: Schultz, Jill
Subject: FW: CCLS Specifications for TESMCFS/01/04

Jill,
I have the following questions regarding Jan's requests below:
1. The collection container I have listed for Hgb adducts is a 10mL K3EDTA as per previous versions of the protocol (6.4). If I simply state, "10mL lavender top EDTA", a K2EDTA may be supplied. Any EDTA tube will have a lavender top. Does it no longer matter whether the EDTA is K2 or K3? If we can use K2, I think we have a plastic tube available (plastic is preferable for safety reasons).

2. The Special Monitoring is mentioned in section VI.A. The details of the monitoring will be in a separate addendum. From the original request, we had planned on weekly reports of all analytes. Do they now only need the analytes that Jan lists?

3. I know we had changed the NNAL to 18mL in 20mL HDPE tubes, but was unaware that the Nicotine had also changed to this quantity (it is in the newest version of the protocol sent yesterday). I had already located 10mL HDPP tubes to use for nicotine but will have to do a search for 20mL HDPP to see if it is available as we do not currently stock this item.

4. Jan questions the quantities of bulk supplies being sent at startup. Please indicate how many of each tube you would like sent to each site. Remember that these are extra tubes. The tubes for each visit will be included in each kit.

Thanks,
Pam

-----Original Message-----
From: Jan.Oey@pmusa.com [mailto:Jan.Oey@pmusa.com]
Sent: Monday, August 30, 2004 2:43 PM
To: Schultz, Jill; Downey, Pamela C.
Subject: RE: CCLS Specifications for TESMCFS/01/04

Dear Jill,

Here are comments:

PM3006573389

Source: https://www.industrydocuments.ucsf.edu/docs/nmdj0001

Page 11-C: Add 1 row for 20 mL HDPP tube.

Are those quantity per sites actually enough? (I understand these are ADDITIONAL supplies, in addition to what is already shipped as kit).

Replace 10 mL K3EDTA with 10 mL lavender top EDTA vacutainer

Page 13 and 14 -C: Specimen Received Under Unexpected Conditions: add Notify Sponsor weekly for nicotine, NNAL, 3- all ana 4/08 HPMA, 1-OHP, and MHBMA

Page 14: replace "francis.montreuil@mdsps.com" with "karen.combs@mdsps.com" for 3-HPMA, 1-OHP, and MHBMA

Page 16: replace "1-10 mL K3EDTA (glass - approved ..... If necessary)" with "1-10mL lavender top, EDTA vacutainer" for Aminobiphenyl Hb adducts

Replace "2-10 mL HDPP" with "2-20 mL HDPP" for nicotine

Add "within 30 hours from the beginning of the 24 hours urine collection" to the Collection Instructions for MHBMA

Regards,
Jan

-----Original Message-----
From: Schultz, Jill [mailto:Jill.Schultz@covance.com]
Sent: Friday, August 27, 2004 8:38 AM
To: Barbara K. Zedler (E-mail 2); Bettie L. Nelson (E-mail); Candace R. Adams (E-mail); Denise. T. Mawyer (E-mail); Hans-Juergen Roethig (E-mail); Jan Oey (E-mail); Mohamadi Sarkar (E-mail); Patrick Noonan (E-mail 2); Robin D. Kinser (E-mail); Shixia Feng (E-mail); Valerie A. King (E-mail); Beth Phillips (E-mail); Caifeng Fu (E-mail); Eileen Burns; Jacqueline Mowitz (E-mail); Kimberly Prchal (E-mail); Maureen Sautter (E-mail); Nathalie Rousselle (E-mail); Peggy Ruhn (E-mail); Vickie Yearby
Cc: Schultz, Jill
Subject: CCLS Specifications for TESMCFS/01/04

Please review the revised draft of the study specifications and contact us with your final comments by 08/31/04.

Regards,

Jill M. Schultz
Project Manager
Covance Laboratories Inc.
608-310-8227 (phone)
608-242-7971 (fax)
608-332-7230 (cell)
jill.schultz@covance.com

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Source: https://www.industrydocuments.ucsf.edu/docs/nmdj0001